

**Supplementary Document to Risk
Assessment of the Impact of Lethality
Standards on Salmonellosis from
Ready-to-Eat Meat and Poultry Products**

**DRAFT for
Public Review and Comment**

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1 Scope of Document

This document provides responses to the supplementary risk management questions concerned with the link between various alternative values of the *required lethality* and the resulting level of public health risk. This link is to be considered across a range of RTE meat and poultry products. This document should be reviewed in addition to the document titled “Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products” which describes the primary effort in the risk assessment process (referred to within this document as risk management Question 1. Full technical details regarding the development of the risk assessment upon which the answers described here are based can be found in the primary document. The risk management questions addressed in this document are:

- *Question 2: What would be the impact of lowering lethality for Salmonella on the following:*
 - (a) *Lethality of Listeria monocytogenes in RTE products,*
 - (b) *Lethality of Escherichia coli O157:H7 in RTE fermented products containing beef?*
- *Question 3: What is the effect on public health if the Salmonella lethality performance standard for roast beef is lowered to 5.0?*
- *Question 4: The current time/temperatures requirements for meat patties are based on a 5-log reduction achieved at a set temperature for a given time. If the 5-log reduction is set as a performance standard, what effect would the use of an integrated lethality (using the come-up and come-down times as part of the calculation) of 5-log have on the reduction of E. coli O157:H7 and Salmonella?*
- *Question 5: If the process for certain products, such as country hams, does not achieve more than a 6-log reduction of Salmonella, what would be the effect of retaining these processes and setting the performance standard as that already achieved?*
- *Question 6: Can the effect on Salmonella incidence from varying lethalitys be determined?*
- *Question 7: What is the effect on public health if only roast beef, cooked meat patties, and cooked poultry have codified performance standards while all other RTE products remained non-codified?*

- *Question 8: What is the effect on public health if only the large plants are required to meet the performance standard? Same for small? Same for very small?*
- *Question 9: What is the effect on public health if implementation is staggered over 5 years (i.e., large within 1 year, small within 3 years, very small within 5 years)?*
- *Question 10: What is the effect on public health if the performance standard is designed to account for production volume instead of HACCP plant size of large (greater than 500 employees), small (fewer than 500 but 10 or more employees), or very small (fewer than 10 employees or less than \$2.5 million annual sales)?*

2 Question 2: Inferring Impact for *Listeria monocytogenes* and *E. coli* O157:H7

What would be the impact of lowering lethality for Salmonella on the following:

- a) Lethality of *Listeria monocytogenes* in RTE products*
- b) Lethality of *E. coli* O157:H7 on RTE fermented products containing beef?*

This question relates to the ability to predict reductions in public health risk for other organisms (*E. coli* O157:H7 and *L. monocytogenes*) based on adherence to varying lethality requirements for *Salmonella spp.*

The specification of a standard does not specify how the standard is achieved, for example is lethality achieved through heat alone, or other treatments? How is the heat applied? A key to making the extrapolation from *Salmonella* to other organisms is to determine the basis upon which one might design and validate the process to achieve a given standard for lethality of *Salmonella spp.* As discussed in the RTI report (RTI, 2004), design and validation of processes may be carried out through challenge studies simulating the actual product and process, through consultation with a process authority with or without the capacity of process simulation, through consultation with the scientific literature, or various combinations thereof. For any given combination of product, process, design methodology, strain or cocktail of strains used for testing, validation and simulation, as well as the diversity in the validation approaches, there is an almost limitless diversity of alternative processes that could be deemed as appropriately meeting the lethality requirements.

Given there is such variation in the way in which a lethality standard may be implemented, and that it is not possible to predict these mechanisms within the scope of this risk assessment, the condition, “validated to have a X-log lethality for *Salmonella*”, while having clearer regulatory implications, can not, on its own,

be meaningfully interpreted as a basis for predicting the lethality achieved for other organisms. To achieve this, an explicit description of each and every process that might be used to apply the standard for each product to be considered would be required. Given the diversity in processes that might satisfy that statement, extrapolation from the statement, “validated to have a X-log lethality for *Salmonella*” to a statement that this corresponds to a “Y-log lethality for another organism” seems to be without a reasonable scientific basis. Even if all the mechanisms of achieving lethality that might be applied were known for particular products, it would not be reasonable to apply the analysis to an entire class of products with highly variable and unknown (proprietary) processing conditions. Even if the process was well specified, within the class of target organisms (i.e., among alternate strains of *E. coli* O157:H7 and *L. monocytogenes*) there will still be considerable diversity in the lethality which would be achieved.

Unless the state of knowledge of the frequency with which specific processing conditions are applied to RTE products, and corresponding experimental data is considerably improved across the range of products considered in this risk assessment, the prediction of the comparative performance by extrapolation of inactivation effectiveness designed for one class of organisms (e.g., salmonellae) to another class (e.g., *Escherichiae* spp. or *Listeria* spp.) is currently inadvisable except in the context of very precise specification of an individual process and product. Even where this were possible, extrapolation of this precisely modeled situation to an entire class of products undergoing highly variable processes would be very difficult to defend.

2.1 Issues in Extrapolating from Salmonella and Estimating Risk from *L. monocytogenes* Survival of Lethality Processes

The dominant source of listeriosis, at least as far as meat and poultry products are concerned is post-process contamination. Various initiatives by industry and other components of FSIS regulations are intended to address this risk.

It would be very difficult to produce a defensible estimate of the population risk associated with surviving *Listeria* spp. in the midst of considerable debate and uncertainty regarding the dominant post-processing (i.e., food contact surface) sources. Even without that concern, the risk assessment of listeriosis resulting from insufficient lethality is effectively dominated by three assumptions: the capacity of a product to support growth of *L. monocytogenes*, the maximum population density achievable by *L. monocytogenes*, and the dose-response parameter assigned. In order to carry out such a risk assessment, the full set of assumptions relating to growth of *Listeria* and its associated dose-response relationship would need to be reconsidered for this assessment. In addition, the product groupings would need to be reconsidered to take into account the dominance of each product’s growth potential in determining the risk associated

with *L. monocytogenes*. As a result, no estimate can be reasonably offered regarding the current level of risk associated only with *L. monocytogenes* that were part of the raw materials and subsequently survive the lethality stage in RTE.

2.2 Issues in Estimating Risk from *E. coli* O157:H7 Surviving Lethality Processes

Although a comparative lethality analysis did not generate a conclusive argument, it can be argued that the assessed impact of lethality on *Salmonella* is a reasonable surrogate for *E. coli* O157:H7. Since there is considerable uncertainty regarding the impact for *Salmonella* and no firm quantitative basis for translating unspecified and widely varying lethality processes from one organism to another, further extrapolation appears to be unjustified scientifically. To pursue this estimation process, considerable further effort and more complete characterization of the actual processing being applied is required, particularly to comminuted RTE fermented beef products. In addition, the product groupings would need to be reconsidered to take into account the need to separate beef and pork raw materials (they are currently grouped for many product classes) on the basis of the prevalence of *E. coli* O157:H7.

3 Question 3: Roast Beef

What is the effect on public health if the Salmonella performance standard for roast beef is lowered to 5.0?

From a qualitative perspective, the risk associated with roast beef can be described as given in Table 3-1.

Table 3-1: Qualitative description of the risks associated with roast beef

Factor	Relative Value	Rationale
Raw Material Pathogen Burden	Low	Intact Beef has a very low pathogen burden per unit mass as the majority is surface contamination
Thermal Process Safety	Large Safety Factor	The majority is surface contamination, resulting in high log-reductions at surface to cook internal meat
Storage and Growth Risk Factor	Higher Risk	Allows resuscitation and growth of surviving pathogens
Reheating	Rarely	Assumes most RTE Roast Beef is consumed as sandwich meat, majority is not reheated
Overall	Low Risk	Lower risk associated with pathogen

		burden and thermal process safety factor dominates the relative risk, making it a relatively low risk product
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The combination of a low pathogen burden and a large safety factor, even allowing for variation in these factors, has a greater impact upon the risk associated with roast beef products than the storage of the product, and any resulting microbial growth. More specifically, although growth may occur during storage, and reheating is assumed a rare event, the contamination levels at storage will be very low due to the combination of a low pathogen burden and thermal process safety factor. The relative safety provided by a low pathogen burden and a large safety factor dominate, making Roast Beef a relatively low risk product.

The number of cases per year for Roast Beef that the risk assessment process described in response to Question 1 generates are given in Table 3-2. For the scenarios with a 5-log reduction, the “Relax to Lower Standard” scenario is applied (see explanation in response to Question 1).

Table 3-2: Number of cases per year from Roast Beef as described in response to Question 1

Scenario	Cases per Annum
5-log; All factors included	0.01
5-log; Excluding Only Reheating	0.01
5-log; Excluding Thermal Process Safety Factor	116
5-log; Excluding Reheating and Thermal Process S.F.	121
6.5-log; All factors included	0.0004
6.5-log; Excluding Only Reheating	0.0004
6.5-log; Excluding Thermal Process Safety Factor	4
6.5-log; Excluding Reheating and Thermal Process S.F.	4

The answer to this question depends largely on the expected implementation of the roast beef standard in terms of how the lethality is measured. If we assume roast beef is an intact product, and processors cook the product in such a way as to achieve a 5.0-log reduction in the deep interior of the product, then the overall effective lethality of the process would be significantly higher than a 5.0 log reduction in *Salmonella*. This is due to the long duration of heating required in the cooking of such products. Assuming that contamination is only on the surface of the product, lowering the performance standard to 5.0 from 6.5 (interpreted as applying to the interior of the product) resulting in slight variations to the necessary internal temperature achieved, would be expected to yield a 30

fold increase in a very small risk (e.g., generating less than one new case per year. This applies to a truly intact product that achieves a very high surface temperature during the cooking process, assuming a minimum of a 4-log thermal process safety factor.

If it is understood that roast beef is intact, and that processors are motivated by basic consumer preference and quality considerations to achieve some internal heating through surface heating, then the effective lethality (considering the pathogens are only on the surface) will be quite high and the public health risk is unlikely to be sensitive to the exact performance standard (assuming it is implemented as applicable to the coolest point in the product, thereby justifying the safety factor assumptions applied). This argument would not apply to products that may be internally compromised through injection or other processes that yield a product that is no longer intact from a contamination perspective. The above logic applies not only to roast beef, but also to any truly intact product that requires considerable surface heating (with regards to combinations of time and temperature) to increase the internal temperature.

4 Question 4: Impact of Integrated Lethality Calculations

The current time/temperatures requirements for meat patties are based on a 5-log reduction achieved at a set temperature for a given time. If the 5-log reduction is set as a performance standard, what effect would the use of an integrated lethality (using the come-up and come-down times as part of the calculation) of 5-log have on the reduction of E. coli O157:H7 and Salmonella?

We can compare the results of integrated lethality versus the current requirements. Using the current 5-log standard (9CFR 318.23, see relevant text in Appendix 1). Given a z-value for *Salmonella* in RTE foods we are able to calculate the log reductions at different cooking temperatures. For example, assuming a z-value of 9.9°F, and a reference D-value of 0.14 at 151 °F, we can establish the log reductions achieved at different temperatures using the formulation:

$$F\text{-value} = 10^{(\text{Temp-Tref})/z\text{-value}}$$

$$\text{Log reduction} = F\text{-value}/D\text{-value}$$

For example, given a range of temperatures from 135 to 155°F the corresponding log reductions are as follows:

Temperature (°F)	F-value	Log Reduction (1 minute)
135	0.02	0.18
140	0.06	0.56
145	0.21	1.81
150	0.77	5.80
155	2.81	18.57

From the above table, one can observe that if the come-up time between 145 and 151 °F lasted as little as one minute, one would achieve at least a 2 log reduction in that time, and more likely a value closer to a 4 log reduction or higher. If cooling followed the same pattern, the same again would be achieved during that cooling phase. If the final core temperature achieved exceeds 151, the effect may be even more pronounced due to the greater log reductions achieved in the same period of time. For example, 30 seconds at 154 °F will achieve a 7 log reduction. As the temperature decreases, however, the contribution to overall lethality rapidly becomes less significant given the assumed reference values.

Consider the three heating patterns given in Table 4-1. The first two rely on holding the patty at 151 °F for 41 seconds to achieve a 5-log reduction. Of these two, the first assumes the core temperature continues to rise during the hold pattern. The second assumes a constant temperature. The third pattern achieves a 5-log reduction using integrated lethality. The example is based on Scott and Weddig (1998). The heating curve was adjusted to achieve a 5-log reduction when taking the mean D-value between any two temperature points instead of using the earlier timepoint to determine the D-value in the interval.

Table 4-1: Heating patterns and associated temperature profile for patties.

Elapsed Time (minutes)	Standard with Peak		Standard with Hold		Elapsed Time (minutes)	Integrated Lethality	
	Center Patty Temp (°F)	Cumulative Log Reduction	Center Patty Temp (°F)	Cumulative Log Reduction		Center Patty Temp (°F)	Cumulative Log Reduction
0.00	40	0.000	40	0.000	0.0	40	0.000
0.50	64	0.000	64	0.000	0.5	64	0.000
1.00	82	0.000	82	0.000	1.0	82	0.000
1.50	97	0.000	97	0.000	1.5	97	0.000
2.00	113	0.000	113	0.000	2.0	113	0.000
2.50	128	0.001	128	0.001	2.5	128	0.001
3.00	138	0.033	138	0.033	3.0	138	0.033
3.50	142	0.287	142	0.287	3.5	142	0.287
4.00	145	0.888	145	0.888	4.0	146	0.932

4.50	148	2.096	148	2.096	4.5	149	2.458
5.00	151	4.527	151	4.527	5.0	146	3.983
5.34	154	7.850	151	7.014	5.5	140	4.436
5.68	151	11.170	151	9.502	6.0	137	4.624
6.18	148	13.600	148	11.930	6.5	136	4.748
6.68	145	14.810	145	13.140	7.0	135	4.846
7.18	140	15.240	140	13.570	7.5	134	4.924
7.68	137	15.430	137	13.760	8.0	133	4.986
8.18	136	15.550	136	13.880	8.5	129	5.017
8.68	130	15.600	130	13.930	9.0	120	5.022
9.18	124	15.610	124	13.940	9.5	112	5.023
9.68	118	15.610	118	13.940	10.0	104	5.023
10.18	104	15.610	104	13.940			

The above example illustrates several points. 1) Applying the current standard to achieve a 5-log reduction may actually achieve a much higher effective reduction (in this case, a 14-15 log reduction); 2) A peak within the hold pattern (in this example, in the period between 5 to 5.68 minutes) may result in achieving greater than a 5-log reduction even within that hold time. 3) Moving to an integrated lethality model would result in a net reduction of effective lethality.

The net effect would vary from process to process depending on its particular heating and cooling pattern. If integrated lethality is considered in isolation of other factors, then the potential exists, in shifting from a mandated holding time at specific temperatures to the use of integrated lethality calculations, to reduce the effective lethality by several logs (i.e, orders of magnitude) at a minimum. Given the binomial survival assumptions stated earlier in this document, this would increase the corresponding public health risk by several logs compared to the impact of the current prescribed guidelines.

There are, however, several mitigating factors. As an example, the public health effect of integrated lethality calculations cannot be completely separated from the impact of the thermal process safety factors that apply for any lethality process. If the temperature measurements being taken are from the coolest point in a product then the overall effective lethality is considerably higher than is represented by the calculation at the coolest point (this is true regardless of whether prescribed time-temperature tables or integrated lethality calculations are applied). The extent to which the rest of the product is considerably more thoroughly cooked than the point which is being measured must also be considered in assessing the impact of integrated lethality calculations.

5 Question 5: Country Hams

If the process for certain products, such as country hams, does not achieve more than a 6-log reduction of Salmonella, what would be the effect of retaining these processes and setting the performance standard as that already achieved?

In answering this question, it is assumed that the relative proportion of processors achieving the standard follows the distribution presented in the RTI report for country hams (RTI, 2004). This report indicates that 10% of processors are achieving lethality of between 5-log and 6.5-log while the remaining 90% are achieving greater than 6.5-log. For present purposes, we assume that the distribution among those achieving less than 6.5-log is uniform between 5.0-log and 6.5-log and that those described as achieving 6.5-log are uniformly distributed between 6.5-log and 7.5-log. The effective lethality of this collective effort is approximately 6.3. If 100% achieved the standard (i.e., all achieving between 6.5 and 7.5 log), the collective lethality would be approximately 6.7.

From a qualitative perspective, the risk associated with country ham can be summarized as given in Table 5-1.

Table 5-1: Qualitative description of the risks associated with country hams

Factor	Relative Value	Rationale
Raw Material Pathogen Burden	Low	Intact Pork has a relatively low pathogen burden per unit mass.
Thermal Process Safety Factor	None	The lethality process does not rely on heat penetration so does not yield over-cooking of parts of the product.
Storage and Growth Risk Factor	Low Risk	Surviving organisms are unlikely to grow where there is high salt content, low water activity.
Reheating	Usually Reheated	Country Ham is assumed to be reheated by many (boiled to reduce saltiness, fried, etc.) but post-processing residual risk largely remains due to the proportion of consumers who do not reheat the product.
Overall	Low Risk	Lower risk associated with pathogen burden, lack of pathogen growth and reheating makes it a relatively low risk product.

The risk assessment process described in response to Question 1 generates the estimates of risk for Country Ham given in Table 5-2. For the scenarios with a 5-log reduction, the “Relax to Lower Standard” scenario is applied (see explanation in response to Question 1 detailed in the primary document). Note that there is no thermal process safety factor applied for Country Ham.

Table 5-2: Number of cases per year associated with country ham as described in response to Question 1

Scenario	Cases per Annum
5-log; All factors included	0.14
5-log; Excluding Only Reheating	0.67
6.5-log; All factors included;	0.014
6.5-log; Excluding Only Reheating	0.067
6.5-log; All factors included; All “Meet or Exceed 6.5”	0.14
6.5-log; Excluding only Reheating; All “Meet or Exceed 6.5”	0.067

Note: The value for the final entries “6.5-log; All factors included; All Meet or Exceed 6.5” is derived from editing the compliance table in the Analytica model to change the proportion of processors achieving between 6.5 (S) and 7.5 (S+1) from 90% to 100%.

As indicated, country ham is estimated qualitatively and quantitatively to be of relatively low risk. By assuming 100% compliance with the 6.5-log standard (compared to the assumption of 90% with a 6.5 log standard), the public health risk estimate *for country ham* does not change. The impact on the broader RTE public health risk estimate would therefore be negligible.

6 Question 6: Salmonella Incidence in RTE Products

Can the effect on Salmonella incidence in RTE products from varying lethalties be determined?

The impact of varying lethality will have an immediate impact on *Salmonella* incidence in RTE products that are not also contaminated during post-processing. However, this should be understood in the context of the Effective Lethality arguments discussed in response to Question 1. The lowest-achieved lethalties (either through inherent process variation, resistant strains, poor compliance or acute process failures) may well dominate the *Salmonella* incidence. It should also be noted that *Salmonella* incidence (as measured in finished product at the plant, or in retail surveys) will include post-lethality contamination of product and therefore does not simply reflect survival of the lethal processing steps.

A recent FSIS publication (Levine et al., 2001) suggests (though numerous disclaimers and caveats regarding the representativeness of the sampling are

included) that contamination rates on the order of 0.05% to 1.5% are possible in some products (as ten year cumulative averages).

This particular evidence of contamination was not included in the analysis because it is not possible to distinguish contamination that results from post-lethality contamination from that resulting from raw material pathogens which have survived the lethality process. The paper cautions that these data should not be considered a representative sample, so the exact implications of these reported contamination rates remain unclear.

This realization suggests a potential role for more discriminatory sampling of RTE products for salmonellae. For failures associated with lethality (particularly in cooked products), surviving pathogens would be expected in the interior of the product (assuming it is not intact). For failures related to post-process contamination, the exterior would seem more likely to be contaminated. Perhaps a sampling plan could be developed to distinguish between surface and core samples of the product. This may provide more insight into the ultimate source of the pathogens found in RTE finished product.

7 Question 7: Currently Codified Products

What is the effect on public health if only roast beef, cooked meat patties, and cooked poultry have codified performance standards while all other RTE products remained non-codified?

Table 7-1 and Table 7-2 summarize the contribution of these three product groups as described in the response to Question 1.

Table 7-1: Number of cases of salmonellosis per product category as estimated in response to Question 1.

RTE Product Category	Product Class Risk (Cases per Year)		
	All 5.0	Split	All 6.5/7.0
Roast Beef, Corned Beef	0.01	0.0004	0.0004
Fully Cooked Beef Patties	0.11	0.11	0.003
Cooked Turkey (non-Deli)	1,250	13	13
Cooked Chicken (Nuggets, Tenders, non-Deli)	40,740	407	407
Cooked Poultry Deli Meat	15,460	155	155
Cooked Chicken Patties	3,541	35	35
Poultry Frankfurters	3,263	33	33

Table 7-2: Number of cases per year by product category and lethality standard as estimated in response to Question 1.

RTE Product Category	Product Class Risk (Cases per Year)	
	Standard	Cases per Year
Roast Beef, Corned Beef	6.5	0.0004
Fully Cooked Beef Patties	5	0.11
Combined Cooked Poultry	7	643

The codification of standards for cooked poultry would appear to be the largest contribution to public health risk reduction among the currently codified standards. Using the All-5 log scenario as an example, the combined group of Cooked Poultry would generate the majority of illnesses. The codification of this category to a 7.0-log standard reduces the overall public health risk more than for any other possible grouping.

It is not clear what the impact of permanent non-codification of other products would be. Currently for non-codified products, processes may be designed, even if not yet required, to approach compliance with a 6.5-log standard. Any number of alternate scenarios for assigning products to different lethality standards, or assumptions regarding compliance can be performed using the user interface in the Analytica model, but it is not possible to provide a definitive statement on the impact of permanent non-codification for other products.

8 Question 8: Impact According to HACCP Plant Size Categories

What is the effect on public health if only the large plants are required to meet the performance standard? Same for small? Same for very small?

Before beginning this analysis, and the analysis for questions 9 and 10, we must first establish the relative proportions for production for each of the HACCP plant sizes. HACCP categories of plant sizes are defined as given in Table 8-1 (FSIS, 1996).

Table 8-1: HACCP categories of plant sizes

Plant Size	Description
Very Small (VS)	Having fewer than 10 employees or annual sales of less than \$2.5 million
Small (S)	Having fewer than 500 but more than 10 employees, and annual sales of \$2.5 million or greater
Large (L)	Having 500 or more employees, and annual sales of \$2.5 million or greater

greater

Using the 1997 US Economic Census Data for Poultry Processing (US Census Bureau, 1999a) and Meat Processed From Carcasses (US Census Bureau, 1999b), we can estimate the relative contribution of each plant size category to total annual production (Table 8-2). Since the mean sales of plants with 10 employees or more is greater than \$2.5 million for both poultry and meat, it is assumed that all plants in this category qualify as small, and not very small. The total value of shipments is taken as a proportional substitute for total mass of shipments to determine the relative contribution to the overall market for each plant size.

Table 8-2: The relative contribution of each plant size category to total annual production

Poultry		
Plant Size	Total Sales (\$1,000)	Fraction of Total Sales (%)
Very Small	33,135	0.1
Small	8,083,166	25.5
Large	23,542,843	74.4
Total	31,656,144	100.0

Meat		
Plant Size	Total Sales (\$1,000)	Fraction of Total Sales (%)
Very Small	386,019	1.5
Small	19,192,229	76.8
Large	5,427,237	21.7
Total	25,005,485	100.0

As discussed in the technical appendix regarding Effective Lethality Calculations, if the Effective Lethality of plants with lower production is appreciably less than the plants with higher production, then they can still readily contribute more public health risk despite their smaller share of production.

For instance, assume the effective lethality (on the log-scale) is 4 for very small plants, 5 for small plants and 6 for large plants. If we assume a total raw material pathogen load of 10^8 organisms distribution in proportion to production in all plants, we can model the relative contribution to public health risk for each plant size as shown in Table 8-3. In this scenario, even though small plants only contribute 25% of production, they may generate 75% of the public health risk. [Note: these tables uses hypothetical inputs, therefore the results are hypothetical].

Table 8-3: Hypothetical public health risk when very small plants are assumed to achieve a 4-log reduction

Using Production Fractions for Poultry					
Plant Size	Lethality Standard	Production Fraction	Pathogen Load	Expected Number of Survivors	Hypothetical % of Public Health Risk
VS	4-log	0.001	1.0×10^5	10	3
S	5-log	0.255	2.6×10^7	255	75
L	6-log	0.744	7.4×10^7	74	22
Effective Lethality	5.5-log	1.000	1.0×10^8	339	100

Using Production Fractions for Meat					
Plant Size	Lethality Standard	Production Fraction	Pathogen Load	Expected Number of Survivors	Hypothetical % of Public Health Risk
VS	4-log	0.015	1.5×10^6	154	16
S	5-log	0.768	7.7×10^7	768	81
L	6-log	0.217	2.2×10^7	22	2
Effective Lethality	5-log	1.000	1.0×10^8	944	100*

*Compensates for rounding error in the sum.

In this scenario, the small plant contributes most to the health risk as expected, but the very small plant contributes 16% of the public health risk with only 1.5% of the production.

Alternatively, consider the scenario in which all three plant sizes are currently meeting the same 5 log lethality standard. Given this assumption, what is the effect of only requiring one of the three plant sizes to meet a new performance standard of 6 logs assuming the same total pathogen load of 10^8 organisms distributed across the production of all plants? Hypothetical results are given in Table 8-4. [Note: this table uses hypothetical inputs therefore the results are hypothetical]. Table 8-5 below indicates the change in the Effective Lethality as a result of changes to the performance on individual plant sizes for poultry.

Table 8-4: Hypothetical public health risk from poultry when all plants are assumed to achieve a 5-log reduction

Poultry (Baseline Scenario: All at 5-log)				
Plant Size	Lethality Standard	Production Fraction	Pathogen Load	Expected Number of Survivors
VS	5-log	0.001	1.0×10^5	1
S	5-log	0.255	2.6×10^7	255
L	5-log	0.744	7.4×10^7	744
Effective Lethality	5-log	1.000	1.0×10^8	1000

Table 8-5: The change in the Effective Lethality as a result of changes to the performance on individual plant sizes for poultry

Poultry		
Proposed Change	Log Reductions by Plant Size (VS, S, L)	Effective Lethality
VS improves to 6-log, others remain unchanged.	6,5,5	5.00
S improves to 6-log, others remain unchanged.	5,6,5	5.11
L improves to 6-log, others remain unchanged.	5,5,6	5.48

This example underlines the importance of the lowest lethality level in determining the Effective Lethality. In this case, without corresponding increases in the large plants, there is very little to be gained by improving the standard for small and very small plants. Even when improving the standard for large plants alone, the effective lethality is undermined by the lower lethality in the smaller plants. Improving the standards for either the small or large plant sizes does improve the effectively lethality, but the effectively lethality remains strongly influenced by whichever plant sizes have the lowest lethality values. [Note: this table uses hypothetical inputs therefore the results are hypothetical]. Table 8-6 below indicates the change in the Effective Lethality as a result of changes to the performance on individual plant sizes for meat.

Table 8-6: The change in the Effective Lethality as a result of changes to the performance on individual plant sizes for meat

Beef (Baseline Scenario: All at 5-log)				
Plant Size	Lethality Standard	Production Fraction	Pathogen Load	Hypothetical Expected Number of Survivors
VS	5-log	0.015	1.5×10^6	15
S	5-log	0.768	7.7×10^7	768
L	5-log	0.217	2.2×10^7	217
Effective Lethality	5-log	1.000	1.0×10^8	1000

Meat		
Proposed Change	Log Reductions by Plant Size (VS, S, L)	Effective Lethality
VS improves to 6-log, others remain unchanged.	6,5,5	5.00
S improves to 6-log, others remain unchanged.	5,6,5	5.51
L improves to 6-log, others remain unchanged.	5,5,6	5.09

This example reinforces the results from the poultry example, except that the roles of the large and small plants are reversed.

9 Question 9: Staggered Implementation

What is the effect on public health if implementation is staggered over 5 years (i.e., large within 1 year, small within 3 years, very small within 5 years)?

The answer to this question is inter-related with the answer to Question 8. The contribution of lower lethality values will continue to influence the overall effective lethality particularly until lower-performing plant sizes are brought into compliance. This is especially true for meat, given the census data, as small plants appear to generate the greater proportion of the meat.

If we assume that the goal is to have uniform performance at 7-log lethality, the effective lethality will be staggered according to Table 9-1a and b. [Note: this table uses hypothetical inputs therefore the results are hypothetical].

Table 9-1a: Effective lethality by year

Poultry		
Timeline	Log Reductions by Plant Size (VS, S, L)	Effective Lethality
Year 0	4,5,6	5.47
Year 1	4,5,7	5.56
Year 3	4,7,7	6.70
Year 5	7,7,7	7.00

Since the effective lethality determines the number of surviving organisms then a change in the effective lethality is proportional to a change in the risk of salmonellosis. In this case, the overall shift will reduce the risk associated with this product by a factor of 100. The reduction is greatest in the phase where small plants are brought to 7-log.

Table 9-2b: Effective lethality by year

Meat		
Timeline	Log Reductions by Plant Size (VS, S, L)	Effective Lethality
Year 0	4,5,6	5.03
Year 1	4,5,7	5.03
Year 3	4,7,7	5.78
Year 5	7,7,7	7.00

In this case, the overall shift will reduce the risk associated with this product by a factor of 100. The reduction is negligible until the small plants, with large market share and a lower level of performance are brought to 7-log in Year 3.

Given an alternate assumption that each plant size starts at the same lethality standard of 5-logs, and the goal is to achieve a 6-log reduction, the staggered implementation has the following effect on the effective lethality of the industry as a whole:

Table 9-3: The effect of staggered implementation on the effective lethality of the industry.

Poultry		
Timeline	Log Reductions by Plant Size (VS, S, L)	Effective Lethality
Year 0	5,5,5	5.000
Year 1	5,5,6	5.481
Year 3	5,6,6	5.996
Year 5	6,6,6	6.00

Meat		
Timeline	Log Reductions by Plant Size (VS, S, L)	Effective Lethality
Year 0	5,5,5	5.00
Year 1	5,5,6	5.09
Year 3	5,6,6	5.94
Year 5	6,6,6	6.00

In this case, the overall shift will be to reduce the public health risk for this product by a factor of 10. In the first year, the risk is negligibly reduced. It is only when small plants phase in the program that the bulk of the reduction in public health risk is achieved.

10 Question 10: Impact by Production Volume

What is the effect on public health if the performance standard is designed to account for production volume instead of HACCP plant size of large (greater than 500 employees), small (fewer than 500 but 10 or more employees), or very small (fewer than 10 employees or less than \$2.5 million annual sales)?

Again, in using the 1997 US Economic Census Data for Poultry Processing (US Census Bureau, 1999a) and Meat Processed From Carcasses (US Census Bureau, 1999b), we can estimate the mean annual production per plant for the aggregate categories of plant sizes provided (see the Table 10-1 below). As expected, the data indicate that mean production and plant size are correlated (i.e. the more employees a plant has, the greater the mean production of that plant). [Note, for meat, the final two categories were aggregated due to census privacy requirements.]

The aggregate nature of the data precludes the grouping of these plants by individual production. This would require access to the original census data.

Table 10-1: The mean annual production per plant for the aggregate categories of plant sizes

Poultry				
Employees	Number of Plants	Total Sales (\$1,000)	Sales per Plant (\$1,000)	Market Share (%)
1 - 4	54	20,437	378	0.06
5 - 9	18	12,698	705	0.04
10 - 19	15	45,863	3,058	0.14
20 - 49	35	381,084	10,888	1.20
50 - 99	34	469,971	13,823	1.48
100 - 249	67	1,867,050	27,866	5.90
250 - 499	79	5,319,198	67,332	16.80
500 - 999	97	10,535,960	108,618	33.28
1,000 - 2,499	70	11,620,985	166,014	36.71
2,500 or more	5	1,385,898	277,180	4.38
Total/Mean	474	31,656,144	66,785	100.00

Meat				
Employees	Number of Plants	Total Sales (\$1,000)	Sales per Plant (\$1,000)	Market Share (%)
1 - 4	293	110,712	378	0.44
5 - 9	176	275,307	1,564	1.10
10 - 19	206	544,359	2,643	2.18
20 - 49	246	1,695,874	6,894	6.78
50 - 99	140	2,636,549	18,832	10.54
100 - 249	143	7,697,172	53,826	30.78
250 - 499	68	6,618,275	97,328	26.47
500 - 999	22	3,889,229	176,783	15.55
1,000 - 2,499	2	1,538,008	512,669	6.15
2,500 or more	1			
Total/Mean	1,297	25,005,485	19,279	100.00

Assuming any staggered implementation will start with the largest producers and integrate the smaller producers at different time intervals, we can use market share to estimate the impact on effective lethality as each smaller plant size is brought to the new standard. Assuming a baseline of a 5-log reduction for all plant sizes, we can determine the increase in effective lethality as each subsequent size category implements a 6-log reduction shown in Table 10-2. [Note: this table uses hypothetical inputs therefore the results are hypothetical]

Table 10-2: The increase in effective lethality as each subsequent size category implements a 6-log reduction

Poultry		
Plant Sizes Remaining at 5-Log	Plant Sizes Shifted to 6-Log	Effective Lethality
All	None	5.00
1-2,499	2,500 or more	5.02
1-999	1,000 or more	5.20
1-499	500 or more	5.48
1-249	250 or more	5.75
1-99	100 or more	5.90
1-49	50 or more	5.95
1-19	20 or more	5.990
1-9	10 or more	5.996
1-5	6 or more	5.997
None	All	6.00

Meat		
Plant Sizes Remaining at 5-Log	Plant Sizes Shifted to 6-Log	Effective Lethality
All	None	5.00
1-999	1,000 or more	5.02
1-499	500 or more	5.09
1-249	250 or more	5.25
1-99	100 or more	5.54
1-49	50 or more	5.71
1-19	20 or more	5.87
1-9	10 or more	5.94
1-5	6 or more	5.98
None	All	6.00

From the above results, we can see that as large plants move to the higher standard, the effective lethality moves from 5 to 5.48 for poultry and from 5 to 5.09 for meat. However, additional gains are made by including only a subset of the small plants, (for example, an effective lethality of 5.9 is achieved for poultry by including plants of 100 employees or greater).

Alternatively, if we assume that plants of less than 100 employees initially have a 4-log reduction while larger plants are achieving a 5-log reduction, Table 10-3 results as each plant size increases to a 6-log reduction. [Note: this table uses hypothetical inputs therefore the results are hypothetical].

Table 10-3: Change in effective lethality from assuming plants of less than 100 employees initially have a 4-log reduction while larger plants are achieving a 5-log reduction

Poultry		
Plant Sizes Remaining at 4 or 5-Log	Plant Sizes Shifted to 6-log	Effective Lethality
All	None	4.89
1-2,4999	2,500 or more	4.91
1-999	1,000 or more	5.05
1-499	500 or more	5.23
1-249	250 or more	5.35
1-99	100 or more	5.41
1-49	50 or more	5.61
1-19	20 or more	5.90
1-9	10 or more	5.96
1-5	6 or more	5.97
None	All	6.00

Meat		
Sizes at 4 or 5-Log	Sizes at 6-Log	Effective Lethality
All	None	4.54
1-999	1,000 or more	4.55
1-499	500 or more	4.57
1-249	250 or more	4.61
1-99	100 or more	4.66
1-49	50 or more	4.94
1-19	20 or more	5.33
1-9	10 or more	5.60
1-5	6 or more	5.84
None	All	6.00

As discussed in earlier sections, any plants achieving only a 4-log reduction can still have a considerable impact on the effective lethality, in effect outweighing their relative share of production. As the per-plant production is directly proportional to the plant size, the overall results show a pattern similar to that discussed in Question 9.

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11 Appendix 1: Relevant Text of 9 CFR 318.23 (relates to Question 4)

§ 318.23 Heat-processing and stabilization requirements for uncured meat patties.

(a) *Definitions.* For purposes of this section, the following definitions shall apply:

(1) *Patty.* A shaped and formed, comminuted, flattened cake of meat food product.

(2) *Comminuted.* A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.

(3) *Partially-cooked patties.* Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(4) *Char-marked patties.* Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(b) *Heat-processing procedures for fully-cooked patties.* (1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

Table 11-1: Permitted heat-processing temperature/Time combinations for fully-cooked patties

Minimum internal temperature at the center of each patty		Minimum holding time after required internal temperature is reached	
(Degrees)		(Time)	
Fahrenheit	Or Centigrade	Minutes	Or seconds
151	66.1	.68	41
152	66.7	.54	32
153	67.2	.43	26
154	67.8	.34	20
155	68.3	.27	16
156	68.9	.22	13
157 (and up)	69.4 (and up)	.17	10